BAUSCH + LOMB
See better. Live better.

Bausch & Lomb (Singapore) Private Limited
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Co. Registration No. 198100424H

MEDICAL DEVICE VOLUNTARY PRODUCT RECALL

LaserEdge® Knives

March 06, 2017

Dear Valued Bausch + Lomb Customer,

Bausch + Lomb is conducting a voluntary recall of LaserEdge® knives due to an increase in complaints of a dull knife edge. We are committed to ensuring that all of our products meet the highest standards of quality and take matters such as this very seriously, which is why we are taking this action.

Through the complaint trending program it has been determined that the following LaserEdge Surgical Knives may have demonstrated higher than normal complaints for dull knives.

If excessive force is required to push a dull knife through the cornea, this may result in:

1) Sub-optimal incision shape, such as short tunnel or lack of multi-plane beveling. The consequence may be incisions that are not watertight, requiring sutures, or inducement of corneal astigmatism.
2) Uncontrolled penetration through the cornea resulting in injury to anterior segment structures, such as iris, capsule, or lens.

The likelihood of adverse events associated with dull blades is very low (5 ppm). This is due to the fact that surgeons are trained to avoid applying excessive force to the eye, thereby mitigating the potential risk from dull blades.

It has come to our attention that some boxes of LaserEdge® Knives have not been as sharp as previous lots of this product. Please review carefully the notes outlined in this letter regarding your LaserEdge® Knives.

According to our records, your facility may have a supply of LaserEdge® that is impacted by this recall. A complete list of affected lots is attached at the end of this letter. Additionally the recall acknowledgment form will be prefilled with the recall lots that your facility has ordered.

We ask that you please quarantine any unused boxes (full and partial) and take the following steps to return the product to Bausch + Lomb at our company's expense:

1. Please review your inventory and hold all unused (full and partial) boxes of LaserEdge knives (6/Box or individual packaged knives) from the following lots.
   See below an example of a LaserEdge product label for ease in identifying the product.

Tyvek Lid

2. Please complete the enclosed Recall Acknowledgement Form and contact Bausch + Lomb representative to arrange for a pickup of the identified product.

   Please contact the Bausch + Lomb team with any questions or concerns regarding this process:
   1. Khor Cherng Yeh,Regulatory Affairs Manager (+603-76808821, ch.khor@inovapharma.com)
   2. Oh Sern Siong,Surgical Sales Manager (+65 97727789, SernSiong.Oh@bausch.com)
   3. [Rep contact]

The decision to conduct this voluntary recall is part of our commitment to quality and customer satisfaction. We greatly appreciate your understanding and prompt assistance, and apologize for any inconvenience this may have caused.

Sincerely,

[redacted]
GRACE GUANG
MANAGING DIRECTOR
BAUSCH & LOMB (SINGAPORE) PRIVATE LIMITED

CC: [Chairman Medical Board]
[Hospital]

Affected SKU & Lot in Singapore

Affected SKU	Affected lot number
E7500	MDNF890
E7510	MAKG530
E7515	MAJW650
	MAJX600
	MAJX610
	MAJX620
	MAJX630
	MAJX800
	MAJX810
	MAJY870
	MAJY880
	MAJY890
	MAJZ090
	MAKA100
	MAKA110
	MAKA120
	MAKF890
	MAKF910
	MAKF920
	MAKV380
	MALW370
	MAMA910
	MAMA920
	MAMM560
	MAMM590
	MAMM600
	MAMM610
	MAQA470
	MASD940
	MAVB450
	MAWA780
	MAWA800
	MAWG540
	MAWH690
	MAWK490
	MAWK500
	MAWL420
	MAWL450
	MAWL560

	MAYJ320
	MAYJ340
	MAYX600
	MAZH340
	MAZT220
	MAZT230
	MBAR650
	MBAR660
	MBBD000
	MBBD640
	MDLV600
	MDNA750
	MDNA940
E7515T	MAKP180
	MALW320
	MAMB810
	MAMK290
	MAMK300
	MAML390
	MARR990
	MAWF640
	MAWG440
	MAWG450
	MAYJ380
E7520	MAJX790
E7551A	MAMN410
	MAMN420
	MAMN430
	MAMN440
	MANB620
	MANB630
	MANX170
	MATW680
	MAVB460
	MAVF030
	MAVR110
	MAVR120
	MAXL160
	MAYJ420
	MBAV170
	MBBV650
	MBBV660

	MBBV690
E7557A	MAMK320
E7559A	MAMN320
	MAMN330
	MAQD840
	MAQM040
	MAQM050
	MAQM270
	MAQW050
	MASD820
	MASD830
	MASD850
	MASS210
	MAVP900
	MAWB190
	MAWF140
	MAWS620
	MAWW330
	MAWW340
	MAWW370
	MBBV830
	MBBV840
	MBBV850
	MBBV860
	MBBV870
	MBBV890
	MBBV900
E7575	MARX090
	MAYW640
E7600	MARZ340
	MAWF130
	MAXL130
	MBPB440
	MBRF780
	MBSY390
	MBTB600

Note: There are other identifiers and/or lots affected globally and should you obtain the device from an overseas dealer, kindly clarify with product owner, Bausch & Lomb Incorporated.

BAUSCH+LOMB

[CUSTOMER NAME]
[ADDRESS LINE 1]
[ADDRESS LINE 2]

Recall Acknowledgement Form

This is to acknowledge receipt of the above referenced recall notification dated March, 06, 2017.

Product Details:
LaserEdge® Knives (6/Box or individually)

Please confirm inventory levels of the affected product at your facility with the 7-digit lot numbers:

Product Code	Lot #	# Received	# Used	# in inventory/to be returned
[code]	[lot#]	[qty]		
[code]	[lot#]	[qty]		
[code]	[lot#]	[qty]		
[code]	[lot#]	[qty]		
[code]	[lot#]	[qty]		
[code]	[lot#]	[qty]		
[code]	[lot#]	[qty]		
[code]	[lot#]	[qty]		

To arrange for a pickup of the identified product, please **call the Bausch + Lomb Customer Service team at Telephone: 1800 278 1421 or email: Esther.Tan@bausch.com**

I hereby certify that I have quarantined the above listed product to prevent use and am awaiting pick up by a Bausch + Lomb representative or agent.

_____ _____

Date Name (Print)

_____ _____

Company Stamp Signature

Please complete, sign and return this form to Bausch & Lomb representative, or
Fax: (65) 6725 8010
Email: Esther.Tan@bausch.com
[customer code]